



**SELECTED COVID-19 VACCINATION REQUIREMENTS FOR HEALTH CARE
PROVIDERS/VACCINATION PROVIDERS ISSUED BY THE STATE OF DELAWARE**

Prepared: February 23, 2021

Purpose

This document is intended to ensure that health care/vaccination providers are aware of requirements issued by the State of Delaware for those who have enrolled to administer COVID-19 vaccinations.

Summary of Requirements

1. **Reporting Vaccination Administrations** – Health care providers or other vaccinating providers who administer immunizations shall report information about the immunization and the person to whom it was given, to DelVAX within 24 hours of administering the dose. Information reported must include the vaccinated person's date of birth, address, phone number, race, ethnicity, date of vaccination, lot number and manufacturer of the vaccine administered, and other information as specified in the Delaware Immunization Information System. (Note: The Division of Public Health emphasizes the importance of recording race and ethnicity in order to evaluate efforts to vaccinate underserved populations. Race and ethnicity need to be complete and accurate. Continued provision of additional vaccine will be contingent upon compliance with data reporting requirements.)
2. **Reporting unused Vaccine** – The health care/vaccination provider must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted. (Note: The Division of Public Health suggests that providers should have plans in place for how to handle unused vaccine.)
3. **Requirements for Reporting Adverse Events** – Health care/vaccination providers must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or <http://vaers.hhs.gov/contact.html>).
4. **Administering Vaccine to Priority Populations** - Vaccinations shall be made available only to persons who meet current criteria for (<https://coronavirus.delaware.gov/vaccine/>). Exceptions are authorized for the purpose of preventing waste or spoilage of vaccine only if vaccine has already been constituted for injection and the vaccinator is unable to locate any person who meets the current criteria and is willing to receive vaccination.
5. **2nd Dose Administration** – Health care/vaccination providers shall administer the second dose of a two-dose series to persons who received a first dose from said provider, if requested. Administration of the second dose shall be a higher priority than administration of a first dose to an unvaccinated person, if vaccine is of insufficient supply to accomplish both. Health care/vaccination providers shall also



be required to administer a second dose to patients of record who have been administered the first dose by a different provider. Health care/vaccination providers shall order sufficient second doses for these purposes. However, if vaccine supply is insufficient, no provider shall be penalized for failure to follow these requirements. (Note: The Division of Public Health recommends that providers schedule the second dose at the time of the first dose, while recognizing that appointments may be rescheduled if supply is inadequate.)

6. **Equitable Access and Ability to Pay** – Health care/vaccination providers are prohibited from denying administration of a COVID-19 vaccination for reasons of race, color, gender, ethnicity, disability, national origin, age, or any other protected status. Further, health care/vaccination providers must make vaccinations available regardless of a person's ability to pay, type of health insurance, administration fees, or participation in a particular provider or network. While providers may seek reimbursement from a health insurance plan, they may not seek any out-of-pocket costs from the vaccine recipient.

Complaints

Complaints regarding conformity to these requirements can be emailed to hspcontact@delaware.gov.

Any health care provider who intentionally or willfully provides or distributes, or who supervises someone who intentionally or willfully provides or distributes the COVID-19 vaccine to any individual who is not authorized to receive such vaccine pursuant to the Vaccination Guidance is guilty of unprofessional conduct as that term is defined in Title 24 and may be subject to licensure discipline. Complaints regarding such conduct should be made to the Division of Professional Regulation at https://delpros.delaware.gov/OH_FileComplaint.

Penalties

Emergency Declaration

- Failure to comply with the data reporting requirements in the Declaration of a State of Emergency or any modification to a Declaration of the State of Emergency may result in a fine as authorized by 16 Del. C. § 107(a) and/or the cessation of vaccine distribution to the noncompliant provider.
- Any failure to comply with the provisions contained in a Declaration of a State of Emergency or any modification to a Declaration of the State of Emergency may constitute a criminal offense. 20 Del. C. §§ 3115 (b); 3116 (9); 3122; 3125. State and local law enforcement agencies are authorized to enforce the provisions of any Declaration of a State of Emergency. Intentionally or willfully providing or distributing, or supervising someone who intentionally or willfully provides or distributes the COVID-19 vaccine to any individual who is not authorized to



receive such vaccine pursuant to the Vaccination Guidance is considered 'unprofessional conduct' as that term is defined in Title 24 and the provider may be subject to licensure discipline.

DHSS Order

- Failure to comply with any order of the Department of Health and Social Services may result in a fine as authorized by 16 *Del. C.* 107(a). Repeated failure to comply with such an order may result in the cessation of vaccine distribution to the noncompliant provider.
- In practice, fines imposed are \$100-\$1000 per violation per day.

Original Source Documents

The requirements listed in this summary can be found in the following documents.

- Governor Carney's *Twenty-Seventh Modification: State of Emergency Declaration, Chapter P Vaccine Administration* (<https://governor.delaware.gov/health-soe/twenty-seventh-modification-state-of-emergency-declaration>). **Designated below as ED.**
- DelVAX Delaware Immunization Information System (IIS) User Agreement (<https://delvax.dhss.delaware.gov/delvax/UserRegistration/NewRegistration/ShowPdf/73921>) **Designated below as DelVAX.**
- CDC Vaccination Program Provider Agreement (<https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>). **Designated below as CDC**
- Order of the Department of Health and Social Services issued February 23, 2021 (<https://coronavirus.delaware.gov/wp-content/uploads/sites/177/2021/02/Vaccine-Order-02-23-21.pdf>) **Designated below as DHSS.**



Unabridged Requirements

Reporting Vaccination Administrations

1. Physicians and other health care providers who give immunizations shall report information about the immunization and the person to whom it was given for addition to the immunization registry in a manner prescribed by the Division Director or designee. **DelVAX**
2. I [the health care provider] will provide immunization data to DelVAX in a timely and accurate manner. **DelVAX**
3. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine Administration Data) for reporting can be found on CDC's website. **CDC**
4. Organization must submit Vaccine Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements. **CDC**
5. All health care providers, facilities, and entities administering COVID-19 vaccination in Delaware must report the vaccination within 24 hours to the Division of Public Health through the Delaware Immunization Information System (DelVAX or its derivative). Health care providers, facilities, and entities administering COVID-19 vaccination in Delaware must request and, when provided, report the vaccinated person's date of birth, address, phone number, race, ethnicity, date of vaccination, lot number and manufacturer of the vaccine administered, and other information as specified in the Delaware Immunization Information System. **ED**

Reporting Unused Vaccine

6. Organization must report the number of doses of COVID-19 vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction. **CDC**

Reporting Adverse events

7. Organization must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or <http://vaers.hhs.gov/contact.html>). **CDC**



Administering Vaccine to Priority Populations

8. All COVID-19 vaccinations shall be made available only to persons who meet current criteria for inoculation as determined by DPH. The phases, criteria, or target population will be established and modified over time by DPH in the form of the State of Delaware's COVID-19 Vaccination Guidance ("Vaccination Guidance") and may be accessed at the following website:
<https://coronavirus.delaware.gov/vaccine/> **ED**
9. No person shall intentionally or willfully provide or distribute COVID-19 vaccine to individuals who are not authorized to receive such vaccine pursuant to the Vaccination Guidance, except as provided herein. Any health care provider who intentionally or willfully provides or distributes, or who supervises someone who intentionally or willfully provides or distributes the COVID-19 vaccine to any individual who is not authorized to receive such vaccine pursuant to the Vaccination Guidance is guilty of unprofessional conduct as that term is defined in Title 24 and may be subject to licensure discipline. **ED**
10. Vaccinations not authorized by the Vaccination Guidance are authorized only for the purpose of preventing waste or spoilage of vaccine, but such vaccination shall only be permitted under following conditions and circumstances:
 - a. COVID-19 vaccine has already been constituted for injection and the vaccinator is unable, after a reasonable and diligent search, to locate any individual prior to such vaccine becoming wasted or spoiled, who is (a) presently authorized by the Vaccination Guidance to receive vaccination, and (b) willing to receive vaccination;
 - b. Any vaccinator providing COVID-19 vaccine to any individual not authorized to receive such vaccine as set forth in the Vaccination Guidance shall maintain written documentation of the reasonable and diligent search set forth in the forgoing subparagraph; and
 - c. Any vaccinator providing COVID-19 vaccine to any individual authorized to receive such vaccine pursuant to the exception set forth herein shall maintain a written log identifying every such individual. **ED**

2nd Dose Administration

11. [Every health care provider administering COVID-19 vaccination in Delaware] shall be willing and able to administer the second dose of a two-dose series to persons who received a first dose from said provider, if so requested by the vaccinated person. Administration of the second dose shall be a higher priority than administration of a first dose to an unvaccinated person, if vaccine is of insufficient supply to accomplish both. **DHSS**



12. [Every health care provider administering COVID-19 vaccination in Delaware] shall be required to administer a second dose to patients of record who have been administered the first dose by a different provider. **DHSS**
13. [Every health care provider administering COVID-19 vaccination in Delaware] shall order sufficient second doses for the purposes of this Order. However, if vaccine supply is insufficient, no provider shall be penalized for failure to follow this order **DHSS**

Equitable Access and Ability to Pay

14. The Department of Health and Social Services prohibits health care providers from denying administration of a COVID-19 vaccination for reasons of race, color, gender, ethnicity, disability, national origin, age, or any other protected status. **DHSS**
15. Organization must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees or coverage status. Organization may seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient. Organization may not seek any reimbursement, including through balance billing, from the vaccine recipient. **CDC**
16. All health care providers, facilities and entities that decide to offer vaccinations shall make those vaccinations available to any person meeting the vaccination criteria without regard to that person's ability to pay, type of health insurance, or participation in any particular provider network. **ED**
17. All health care providers, facilities and entities that offer vaccinations shall provide vaccinations at no out-of-pocket cost to individuals. **ED**